

FOR PUBLICATION

**UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

SAFER CHEMICALS, HEALTHY
FAMILIES; ALASKA COMMUNITY
ACTION ON TOXICS;
ENVIRONMENTAL HEALTH STRATEGY
CENTER; ENVIRONMENTAL WORKING
GROUP; LEARNING DISABILITIES
ASSOCIATION OF AMERICA; SIERRA
CLUB; UNION OF CONCERNED
SCIENTISTS; UNITED STEEL, PAPER
AND FORESTRY, RUBBER,
MANUFACTURING, ENERGY, ALLIED
INDUSTRIAL AND SERVICE WORKERS
INTERNATIONAL UNION, AFL-
CIO/CLC; WE ACT FOR
ENVIRONMENTAL JUSTICE; ASBESTOS
DISEASE AWARENESS
ORGANIZATION; VERMONT PUBLIC
INTEREST RESEARCH GROUP,
Petitioners,

No. 17-72260

v.

U.S. ENVIRONMENTAL PROTECTION
AGENCY; ANDREW WHEELER,*

* Andrew Wheeler has been substituted for his predecessor, Scott Pruitt, under Fed. R. App. P. 43(c)(2).

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Administrator, United States
Environmental Protection Agency,
Respondents,

AMERICAN CHEMISTRY COUNCIL;
AMERICAN COATINGS ASSOCIATION;
AMERICAN COKE AND COAL
CHEMICALS INSTITUTE; AMERICAN
FOREST & PAPER ASSOCIATION;
AMERICAN FUEL & PETROCHEMICAL
MANUFACTURERS; AMERICAN
PETROLEUM INSTITUTE; BATTERY
COUNCIL INTERNATIONAL; CHAMBER
OF COMMERCE OF THE UNITED
STATES OF AMERICA; EPS INDUSTRY
ALLIANCE; IPC INTERNATIONAL,
INC., doing business as IPC
Association Connecting Electronics
Industries; NATIONAL ASSOCIATION
OF CHEMICAL DISTRIBUTORS;
NATIONAL MINING ASSOCIATION;
POLYURETHANE MANUFACTURERS
ASSOCIATION; SILVER
NANOTECHNOLOGY WORKING
GROUP; SOCIETY OF CHEMICAL
MANUFACTURERS AND AFFILIATES;
STYRENE INFORMATION AND
RESEARCH CENTER; UTILITY SOLID
WASTE ACTIVITIES GROUP,
Respondents-Intervenors.

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ENVIRONMENTAL DEFENSE FUND,
Petitioner,

No. 17-72501

v.

U.S. ENVIRONMENTAL PROTECTION
AGENCY; ANDREW WHEELER,
Administrator, United States
Environmental Protection Agency,
Respondents,

AMERICAN CHEMISTRY COUNCIL;
AMERICAN COATINGS ASSOCIATION;
AMERICAN COKE AND COAL
CHEMICALS INSTITUTE; AMERICAN
FOREST & PAPER ASSOCIATION;
AMERICAN FUEL & PETROCHEMICAL
MANUFACTURERS; AMERICAN
PETROLEUM INSTITUTE; BATTERY
COUNCIL INTERNATIONAL; CHAMBER
OF COMMERCE OF THE UNITED
STATES OF AMERICA; EPS INDUSTRY
ALLIANCE; IPC INTERNATIONAL,
INC., doing business as IPC
Association Connecting Electronics
Industries; NATIONAL ASSOCIATION
OF CHEMICAL DISTRIBUTORS;
NATIONAL MINING ASSOCIATION;
POLYURETHANE MANUFACTURERS
ASSOCIATION; SILVER
NANOTECHNOLOGY WORKING
GROUP; SOCIETY OF CHEMICAL
MANUFACTURERS AND AFFILIATES;
STYRENE INFORMATION AND

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RESEARCH CENTER; UTILITY SOLID
WASTE ACTIVITIES GROUP,
Respondents-Intervenors.

ALLIANCE OF NURSES FOR HEALTHY
ENVIRONMENTS; CAPE FEAR RIVER
WATCH; NATURAL RESOURCES
DEFENSE COUNCIL,

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION
AGENCY,

Respondent,

AMERICAN CHEMISTRY COUNCIL;
AMERICAN COATINGS ASSOCIATION;
AMERICAN COKE AND COAL
CHEMICALS INSTITUTE; AMERICAN
FOREST & PAPER ASSOCIATION;
AMERICAN FUEL & PETROCHEMICAL
MANUFACTURERS; AMERICAN
PETROLEUM INSTITUTE; BATTERY
COUNCIL INTERNATIONAL; CHAMBER
OF COMMERCE OF THE UNITED
STATES OF AMERICA; EPS INDUSTRY
ALLIANCE; IPC INTERNATIONAL,
INC., doing business as IPC
Association Connecting Electronics
Industries; NATIONAL ASSOCIATION
OF CHEMICAL DISTRIBUTORS;
NATIONAL MINING ASSOCIATION;

No. 17-72968

EPA No.
EPA-HQ-OPPT-
2016-0636

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POLYURETHANE MANUFACTURERS
ASSOCIATION; SILVER
NANOTECHNOLOGY WORKING
GROUP; SOCIETY OF CHEMICAL
MANUFACTURERS AND AFFILIATES;
STYRENE INFORMATION AND
RESEARCH CENTER; UTILITY SOLID
WASTE ACTIVITIES GROUP,
Respondents-Intervenors.

ALLIANCE OF NURSES FOR HEALTHY
ENVIRONMENTS; CAPE FEAR RIVER
WATCH; NATURAL RESOURCES
DEFENSE COUNCIL,
Petitioners,

No. 17-73290

EPA No.
EPA-HQ-OPPT-
2016-0654

v.

U.S. ENVIRONMENTAL PROTECTION
AGENCY,
Respondent,

AMERICAN CHEMISTRY COUNCIL;
AMERICAN COATINGS ASSOCIATION;
AMERICAN COKE AND COAL
CHEMICALS INSTITUTE; AMERICAN
FOREST & PAPER ASSOCIATION;
AMERICAN FUEL & PETROCHEMICAL
MANUFACTURERS; AMERICAN
PETROLEUM INSTITUTE; BATTERY
COUNCIL INTERNATIONAL; CHAMBER
OF COMMERCE OF THE UNITED
STATES OF AMERICA; EPS INDUSTRY

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ALLIANCE; IPC INTERNATIONAL,
INC., doing business as IPC
Association Connecting Electronics
Industries; NATIONAL ASSOCIATION
OF CHEMICAL DISTRIBUTORS;
NATIONAL MINING ASSOCIATION;
POLYURETHANE MANUFACTURERS
ASSOCIATION; SILVER
NANOTECHNOLOGY WORKING
GROUP; SOCIETY OF CHEMICAL
MANUFACTURERS AND AFFILIATES;
STYRENE INFORMATION AND
RESEARCH CENTER; UTILITY SOLID
WASTE ACTIVITIES GROUP,
Respondents-Intervenors.

ENVIRONMENTAL DEFENSE FUND,
Petitioner,

v.

U.S. ENVIRONMENTAL PROTECTION
AGENCY; ANDREW WHEELER,
Administrator, United States
Environmental Protection Agency,
Respondents,

AMERICAN CHEMISTRY COUNCIL;
AMERICAN COATINGS ASSOCIATION;
AMERICAN COKE AND COAL
CHEMICALS INSTITUTE; AMERICAN
FOREST & PAPER ASSOCIATION;
AMERICAN FUEL & PETROCHEMICAL

No. 17-73383

EPA No.
EPA-HQ-OPPT-
2016-0654

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MANUFACTURERS; AMERICAN
 PETROLEUM INSTITUTE; BATTERY
 COUNCIL INTERNATIONAL; CHAMBER
 OF COMMERCE OF THE UNITED
 STATES OF AMERICA; EPS INDUSTRY
 ALLIANCE; IPC INTERNATIONAL,
 INC., doing business as IPC
 Association Connecting Electronics
 Industries; NATIONAL ASSOCIATION
 OF CHEMICAL DISTRIBUTORS;
 NATIONAL MINING ASSOCIATION;
 POLYURETHANE MANUFACTURERS
 ASSOCIATION; SILVER
 NANOTECHNOLOGY WORKING
 GROUP; SOCIETY OF CHEMICAL
 MANUFACTURERS AND AFFILIATES;
 STYRENE INFORMATION AND
 RESEARCH CENTER; UTILITY SOLID
 WASTE ACTIVITIES GROUP,
Respondents-Intervenors.

SAFER CHEMICALS, HEALTHY
 FAMILIES; ALASKA COMMUNITY
 ACTION ON TOXICS;
 ENVIRONMENTAL HEALTH STRATEGY
 CENTER; ENVIRONMENTAL WORKING
 GROUP; LEARNING DISABILITIES
 ASSOCIATION OF AMERICA; SIERRA
 CLUB; UNION OF CONCERNED
 SCIENTISTS; UNITED STEEL, PAPER
 AND FORESTRY, RUBBER,
 MANUFACTURING, ENERGY, ALLIED
 INDUSTRIAL AND SERVICE WORKERS

No. 17-73390

EPA No.
 EPA-HQ-OPPT-
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INTERNATIONAL UNION, AFL-
CIO/CLC; WE ACT FOR
ENVIRONMENTAL JUSTICE; ASBESTOS
DISEASE AWARENESS
ORGANIZATION; VERMONT PUBLIC
INTEREST RESEARCH GROUP,
Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION
AGENCY; ANDREW WHEELER,
Administrator, United States
Environmental Protection Agency,
Respondents,

AMERICAN CHEMISTRY COUNCIL;
AMERICAN COATINGS ASSOCIATION;
AMERICAN COKE AND COAL
CHEMICALS INSTITUTE; AMERICAN
FOREST & PAPER ASSOCIATION;
AMERICAN FUEL & PETROCHEMICAL
MANUFACTURERS; AMERICAN
PETROLEUM INSTITUTE; BATTERY
COUNCIL INTERNATIONAL; CHAMBER
OF COMMERCE OF THE UNITED
STATES OF AMERICA; EPS INDUSTRY
ALLIANCE; IPC INTERNATIONAL,
INC., doing business as IPC
Association Connecting Electronics
Industries; NATIONAL ASSOCIATION
OF CHEMICAL DISTRIBUTORS;
NATIONAL MINING ASSOCIATION;
POLYURETHANE MANUFACTURERS

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ASSOCIATION; SILVER
NANOTECHNOLOGY WORKING
GROUP; SOCIETY OF CHEMICAL
MANUFACTURERS AND AFFILIATES;
STYRENE INFORMATION AND
RESEARCH CENTER; UTILITY SOLID
WASTE ACTIVITIES GROUP,
Respondents-Intervenors.

On Petition for Review of an Order of the
Environmental Protection Agency

Argued and Submitted May 16, 2019
Seattle, Washington

Filed November 14, 2019

Before: Diarmuid F. O'Scannlain and Michelle T.
Friedland, Circuit Judges, and William H. Pauley III,**
District Judge.

Opinion by Judge Friedland

** The Honorable William H. Pauley III, United States District Judge
for the Southern District of New York, sitting by designation.

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SUMMARY***

Environmental Law

The panel dismissed in part, granted in part, and denied in part petitions for review brought by a variety of environmental groups and other organizations, seeking review of a rule promulgated by the United States Environmental Protection Agency (“EPA”) establishing a process to evaluate the health and environmental risks of chemical substances.

The EPA promulgated the Risk Evaluation Rule pursuant to the Toxic Substances Control Act (“TSCA”).

Petitioners argued that TSCA required EPA to evaluate risks from uses of a chemical substance collectively, and that the Risk Evaluation Rule contradicted this mandate. The panel held that this challenge was not justiciable because petitioners’ interpretation of what the EPA intended to do and petitioners’ resulting theory of injury were too speculative. The panel further held that because petitioners’ theory of injury was dependent upon harm caused by a failure to assess all conditions of use together, and because it was very uncertain whether EPA ever planned to do what petitioners feared, petitioners’ alleged injury was too speculative at this time to establish Article III jurisdiction.

Petitioners also argued that the Risk Evaluation Rule expressed an impermissible intent to exclude some

*** This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

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conditions of use from the scope of a risk evaluation, thereby contravening TSCA's requirement that EPA consider all of a chemical's conditions of use. With respect to petitioners' challenge to language in the preamble to the Risk Evaluation Rule, the panel held that it was not final agency action, and thus not reviewable under the Administrative Procedure Act. With respect to petitioners' challenges to specific provisions of the Risk Evaluation Rule, the panel held that the challenges were justiciable final agency action. The panel further held that petitioners had standing to challenge these provisions, and that the challenge was ripe. The panel concluded that the Rule's scope provisions failed on the merits because the challenged provisions did not in fact assert discretion to exclude conditions of use from evaluation.

Finally, petitioners challenged EPA's categorical exclusion of legacy activities from the definition of "conditions of use." The panel held that this claim was justiciable. Turning to the merits, the panel held that EPA's exclusion of legacy uses and associated disposals contradicted TSCA's plain language, but that EPA's exclusion of legacy disposals did not.

COUNSEL

Sarah C. Tallman (argued), Natural Resources Defense Council, Chicago, Illinois; Nancy S. Marks, Natural Resources Defense Council, New York, New York; for Petitioners Alliance of Nurses for Healthy Environments; Cape Fear River Watch; and Natural Resources Defense Council.

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Robert M. Sussman, Sussman and Associates, Washington, D.C.; for Petitioners Safer Chemicals, Healthy Families; Asbestos Disease Awareness Organization; and Vermont Public Interest Research Group.

Robert P. Stockman, Environmental Defense Fund, Washington, D.C.; for Petitioner Environmental Defense Fund.

Eve C. Gartner, Earthjustice, New York, New York; Tosh Sagar, Earthjustice, Washington, D.C.; for Petitioners Alaska Community Action on Toxics; Environmental Health Strategy Center; Environmental Working Group; Learning Disabilities Association of America; Sierra Club; Union of Concerned Scientists; and WE ACT for Environmental Justice.

Randy S. Rabinowitz, OSH Law Project LLC, Washington D.C.; for Petitioner United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO/CLC.

Samara M. Spence (argued) and Erica M. Zilioli, Environmental Defense Section, Environment and Natural Resources Division, United States Department of Justice, Washington, D.C.; Jonathan D. Brightbill, Deputy Assistant Attorney General; Jeffrey H. Wood, Acting Assistant Attorney General; Laurel Celeste, Office of the General Counsel, United States Environmental Protection Agency, Washington, D.C.; for Respondents.

Peter D. Keisler (argued), Samuel B. Boxerman, Timothy K. Webster, C. Frederick Beckner III, Judah Prero, and Samina M. Bharmal, Sidley Austin LLP, Washington, D.C.; for Respondents-Intervenors American Chemistry Council;

SAFER CHEMICALS, HEALTHY FAMILIES V. USEPA 13

American Coke and Coal Chemicals Institute; American Petroleum Institute; American Forest & Paper Association; American Fuel & Petrochemical Manufacturers; Chamber of Commerce of the United States Of America; EPS Industry Alliance; IPC International, Inc.; National Association of Chemical Distributors; National Mining Association; and Silver Nanotechnology Working Group.

David B. Weinberg, Martha E. Marrapese, and Roger H. Miksad, Wiley Rein LLP, Washington, D.C.; for Respondents-Intervenors American Coatings Association and Battery Council International.

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James W. Conrad, Jr., Conrad Law & Policy Counsel, Washington, D.C.; for Respondent-Intervenor Society of Chemical Manufacturers and Affiliates.

Peter L. de la Cruz, Keller and Heckman LLP, Washington, D.C.; for Respondent-Intervenor Styrene Information and Research Center, Inc.

Douglas H. Green and Allison D. Foley, Venable LLP, Washington, D.C.; for Respondent-Intervenor Utility Solid Waste Activities Group.

Richard Moskowitz and Taylor Hoverman, American Fuel & Petrochemical Manufacturers, Washington, D.C.; for Respondent-Intervenor American Fuel & Petrochemical Manufacturers.

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Steven P. Lehotsky and Michael B. Schon, U.S. Chamber Litigation Center, Washington, D.C.; for Respondent-Intervenor Chamber of Commerce of the United States of America.

David S. Muraskin and Leah M. Nicholls, Public Justice P.C., Washington, D.C.; for Amici Curiae American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, and the American Public Health Association.

Paul Olszowka, Barnes & Thornburg LLP, Chicago, Illinois; for Amicus Curiae People for the Ethical Treatment of Animals.

OPINION

FRIEDLAND, Circuit Judge:

Petitioners, a variety of environmental groups and other organizations, seek review of a rule promulgated by the United States Environmental Protection Agency (“EPA” or “the Agency”) establishing a process to evaluate the health and environmental risks of chemical substances. EPA promulgated the “Risk Evaluation Rule” under its authority granted by 15 U.S.C. § 2605(b)(4)(B), a provision added in 2016 to the Toxic Substances Control Act (“TSCA”), 15 U.S.C. § 2601 *et seq.*¹ Petitioners argue that provisions in the Risk Evaluation Rule relating to the Agency’s evaluation of the risks from a substance’s “conditions of

¹ Unless otherwise specified, all references to TSCA’s provisions in title 15 of the United States Code are to the current version, which was amended in 2016.

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use” violate several of TSCA’s requirements. Specifically, Petitioners argue: (1) that TSCA requires EPA to evaluate risks associated with a chemical’s uses collectively before determining that the chemical is safe; (2) that EPA must consider all of a chemical’s conditions of use in that evaluation; and (3) that, when considering conditions of use, EPA must evaluate past disposals of all chemicals, as well as the use and subsequent disposal of chemicals not currently or prospectively manufactured or distributed in commerce for that use. Petitioners argue that various provisions of the Risk Evaluation Rule demonstrate that EPA will not do any of these three things.²

We hold that we lack jurisdiction to review Petitioners’ first challenge, and that their second fails on the merits. But we grant in part the Petition for Review with respect to Petitioners’ third challenge.³

² Petitioners also argue that EPA’s simultaneously promulgated “Prioritization Rule” incorporates some of these alleged deficiencies in the Risk Evaluation Rule, and that the provisions doing so are likewise unlawful. Because Petitioners’ challenges to the Prioritization Rule are entirely encompassed within their challenges to the Risk Evaluation Rule, the challenges rise or fall together. We thus focus only on the Risk Evaluation Rule.

³ Petitioners also challenge several information-gathering provisions in both the Risk Evaluation Rule and the Prioritization Rule. *See* 15 U.S.C. § 2625(k). EPA agrees that some of these challenged information-gathering provisions should be reconsidered and therefore requests that they be remanded. We address the information-gathering issues in a concurrently filed memorandum disposition.

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I.

A.

Congress enacted TSCA in 1976 “to prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances.” S. Rep. No. 94-698, at 1 (1976), *as reprinted in* 1976 U.S.C.C.A.N. 4491, 4491. TSCA was “designed to fill a number of regulatory gaps” in premarket review, regulation of chemicals themselves (rather than regulation of discharges, emissions, ambient air, or consumer products), and information-gathering responsibility. *Id.* at 1–2. TSCA required EPA to regulate chemical substances that the Agency found to “present an unreasonable risk of injury to health or the environment.” 15 U.S.C. § 2605(a) (1976). As originally enacted, however, TSCA did not provide a specific process or timeline by which EPA was required to evaluate a substance’s risks.

In the decades following TSCA’s passage, Congress found that “effective implementation of TSCA by [EPA] ha[d] been challenged by shortcomings in the statute itself, and by several key decisions of Federal Courts and the Agency’s interpretation of those decisions.” S. Rep. No. 114-67, at 2 (2015). There had “been persistent concerns about the pace of EPA’s work under TSCA, the ability of the Agency to use its existing authority, and whether the statute prevent[ed] certain regulatory efforts.” H.R. Rep. No. 114-176, at 12–13 (2015), *as reprinted in* 2016 U.S.C.C.A.N. 276, 277. Congress accordingly amended TSCA in 2016. *See* Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448 (2016) (codified at 15 U.S.C. § 2601 *et seq.*); *see also generally* S. Rep. No. 114-67; H.R. Rep. No. 114-176.

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The 2016 amendments “restructur[ed] the way . . . chemicals are evaluated and regulated,” H.R. Rep. No. 114-176, at 13, but Congress’s policy goals reflected in the 1976 Act remained “intact,” S. Rep. No. 114-67, at 7. Congress intended through the amendments “to provide broad protection of human health and the environment,” and “to improve availability of information about chemicals.” S. Rep. No. 114-67, at 6.

B.

The 2016 amendments create, among other things, “a separate risk evaluation process for determining whether a chemical substance presents or will present an unreasonable risk of injury,” and prescribe statutory deadlines by which EPA is required to complete such evaluations. H.R. Rep. No. 114-176, at 23, 25. The amendments also direct EPA’s Administrator to prioritize evaluations of the risks of chemicals considered to be the most dangerous. And once EPA determines that a particular chemical substance is associated with an unreasonable risk, the Agency is required to regulate that substance.

With respect to prioritizing risk evaluations, TSCA requires that the Administrator “designate as a high-priority substance a chemical substance that the Administrator concludes . . . may present an unreasonable risk of injury to health or the environment . . . under the conditions of use.” 15 U.S.C. § 2605(b)(1)(B)(i). The Administrator must designate a substance as “low-priority” if “such substance does not meet the standard” to be high-priority. 15 U.S.C. § 2605(b)(1)(B)(ii).

For chemical substances that EPA designates as high-priority, the Agency must initiate and complete a risk evaluation of the chemical within three years, with a possible

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six-month extension. 15 U.S.C. § 2605(b)(3)(A), (b)(4)(G). EPA must also conduct some risk evaluations at the request of chemical manufacturers (“manufacturer-requested risk evaluations”). *See* 15 U.S.C. § 2605(b)(4)(C)(ii).

TSCA’s risk evaluation provision requires EPA to evaluate chemical substances under their “conditions of use.” Specifically, TSCA states:

The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.

15 U.S.C. § 2605(b)(4)(A).

The term “conditions of use” is defined to mean “the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” 15 U.S.C. § 2602(4).⁴ In the early stages of the risk evaluation process, TSCA requires EPA to list in a published scope document

⁴ TSCA provides statutory definitions for the terms “manufacture,” “process,” and “commerce” (as well as “distribute in commerce” and “distribution in commerce”), but does not define “used” or “disposed of.” *See generally* 15 U.S.C. § 2602.

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the conditions of use it “expects to consider” for the chemical substance being evaluated. 15 U.S.C. § 2605(b)(4)(D).

Once a risk evaluation is completed, if the Administrator determines based on that evaluation “that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall” promulgate rules regulating that chemical substance so that it “no longer presents such [an unreasonable] risk.” 15 U.S.C. § 2605(a); *see also* 15 U.S.C. § 2605(c)(1).

In order to effectuate TSCA’s statutory requirements, Congress instructed EPA to “establish, by rule, a risk-based screening process, including criteria for designating chemical substances as” either high-priority or low-priority for risk evaluation. 15 U.S.C. § 2605(b)(1)(A). EPA was also required to establish by rule “a process to conduct risk evaluations.” 15 U.S.C. § 2605(b)(4)(B).

TSCA also contains a judicial review provision. *See* 15 U.S.C. § 2618. It provides that “not later than 60 days after the date on which a rule is promulgated . . . or the date on which an order is issued [under TSCA] any person may file a petition for judicial review of such rule or order.” 15 U.S.C. § 2618(a)(1)(A). TSCA specifically authorizes judicial review of EPA’s determination that a substance is low-priority or poses no unreasonable risk. 15 U.S.C. § 2618(a)(1)(A), (a)(1)(C)(i).

C.

In accordance with TSCA, EPA issued rules for prioritization and risk evaluation in July 2017. The Risk

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Evaluation Rule states, generally, that EPA will evaluate chemical substances under their conditions of use:

As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of uses [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents.

40 C.F.R. § 702.47.

The Risk Evaluation Rule similarly explains that “[t]he scope of the risk evaluation will include,” among other things, “[t]he condition(s) of use, as determined by the Administrator, that the EPA plans to consider in the risk evaluation.” 40 C.F.R. § 702.41(c). “Conditions of use” is defined in the Risk Evaluation Rule as “the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of”—the same definition as in TSCA itself. *Compare* 40 C.F.R. § 702.33, *with* 15 U.S.C. § 2602(4).

In the preamble to the Risk Evaluation Rule, EPA states that three categories of uses and activities are excluded from the definition of conditions of use. Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726, 33,729 (July 20, 2017). These are: (1) “circumstances associated with activities that do not reflect ongoing or prospective manufacturing, processing, or distribution,” which the Agency calls “legacy uses”; (2) “disposals from such uses,” which the Agency calls “associated disposal”; and (3) “disposals that have already occurred,” which the Agency calls “legacy

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disposal.” *Id.* In this litigation, EPA refers to these uses and activities collectively as “legacy activities.”

EPA also states, in the preamble to the Risk Evaluation Rule, that it “intends to exercise discretion in addressing circumstances where [a] chemical substance . . . is unintentionally present as an impurity in another chemical substance that is not the subject of the pertinent scoping.” 82 Fed. Reg. at 33,730. In some circumstances, EPA states, “it may be most appropriate . . . to evaluate the potential risks arising from a chemical impurity within the scope of the risk evaluations for the impurity itself,” while in others it “may be more appropriate to evaluate such risks within the scope of the risk evaluation for the separate chemical substances that bear the impurity.” *Id.* The preamble further provides that the Agency “may choose not to include [that] impurity within the Scope of any risk evaluation,” where “the risk from the presence of the impurity would be ‘*de minimis*’ or otherwise insignificant.” *Id.* The preamble also lists several other uses that commenters had suggested should not be considered in risk evaluations, such as misuse and illegal use. *Id.* The preamble ultimately concludes, however, that “it would be premature to definitively exclude a priori specific conditions of use from risk evaluation.” *Id.*

D.

Several groups filed petitions for review of the Risk Evaluation Rule pursuant to the judicial review provisions of TSCA, 15 U.S.C. § 2618, and the Administrative Procedure Act, 5 U.S.C. § 706. Those petitions were consolidated.⁵ A

⁵ Petitioners in this consolidated action are: Safer Chemicals, Healthy Families; Alaska Community Action on Toxics; Environmental Health Strategy Center; Environmental Working Group; Learning

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number of industry groups jointly moved to intervene, and a motions panel of our court granted the motion.⁶

Petitioners argue that TSCA requires EPA to evaluate risks from uses of a chemical substance collectively, and that the Risk Evaluation Rule contradicts this mandate. Separately, Petitioners argue that the Risk Evaluation Rule expresses an impermissible intent to exclude some conditions of use from the scope of a risk evaluation. Finally, Petitioners challenge EPA's exclusion of legacy activities from the definition of "conditions of use."

II.

A.

Petitioners first challenge provisions of the Risk Evaluation Rule relating to the process by which EPA will conduct risk determinations. Petitioners argue that several

Disabilities Association of America; Sierra Club; Union of Concerned Scientists; United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO/CLC; WE ACT for Environmental Justice; Asbestos Disease Awareness Organization; Vermont Public Interest Research Group; Alliance of Nurses for Healthy Environments; Cape Fear River Watch; Natural Resources Defense Council; and Environmental Defense Fund.

⁶Intervenors are: American Chemistry Council; American Coatings Association; American Coke and Coal Chemicals Institute; American Forest & Paper Association; American Fuel & Petrochemical Manufacturers; American Petroleum Institute; Battery Council International; Chamber of Commerce of the United States of America; EPS Industry Alliance; IPC International, Inc.; National Association of Chemical Distributors; National Mining Association; Polyurethane Manufacturers Association; Silver Nanotechnology Working Group; Society of Chemical Manufacturers and Affiliates; Styrene Information and Research Center, Inc.; and Utility Solid Waste Activities Group.

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provisions in the Rule assert that EPA has authority to determine whether individual conditions of use, in isolation, pose unreasonable risks, rather than to evaluate the risks posed by a chemical substance holistically. Specifically, Petitioners challenge three provisions of the Rule. First is EPA's statement that it "will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of use[] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents." *See* 40 C.F.R. § 702.47. Second is the Rule's statement that:

EPA will complete the risk evaluation of the chemical substance addressing all of the conditions of use within the scope of the evaluation. However, EPA may complete its evaluation of the chemical substance under specific conditions of use or categories of conditions of use at any point following the issuance of the final scope document, and issue its determination as to whether the chemical substance under those conditions of use does or does not present an unreasonable risk to health or the environment under those conditions of use.

40 C.F.R. § 702.41(a)(9).

Finally, Petitioners challenge a provision of the Rule entitled "Final determination of no unreasonable risk," which states:

A determination by EPA that the chemical substance, under one or more of the conditions of use within the scope of the risk evaluation, does not present an unreasonable

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risk of injury to health or the environment
will be issued by order and considered to be
a final Agency action.

40 C.F.R. § 702.49(d).

Petitioners interpret these provisions to mean that EPA plans to conduct use-by-use risk determinations and to declare the safety of individual uses of a chemical standing alone, without first considering whether its conditions of use, viewed together, pose an unreasonable risk. Petitioners argue that this contravenes TSCA's requirement that EPA "conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk . . . under the conditions of use." *See* 15 U.S.C. § 2605(b)(4)(A). Petitioners emphasize TSCA's reference to the risk of "*a chemical substance*," arguing that this requires the agency to conduct a holistic assessment of a chemical under all of its conditions of use, rather than to assess risks from individual conditions of use.

Petitioners recognize that when EPA decides that a particular condition of use *does* pose an unreasonable risk, such a determination on its own complies with TSCA's requirement that EPA conduct an evaluation of whether "the substance as a whole poses unreasonable risk." That is because, as Petitioners explain, if any condition of use (or any combination of subsets of the conditions of use) associated with a chemical poses an unreasonable risk of harm, that chemical substance would necessarily pose an unreasonable risk under *all* of its conditions of use considered together. As soon as the Agency determines that any combination of conditions of use pose such a risk, therefore, the Agency may proceed to regulate that chemical under 15 U.S.C. § 2605(a). Petitioners contend that the Risk

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Evaluation Rule goes one step further, however, allowing EPA to issue a final determination that a chemical substance does *not* pose an unreasonable risk after having looked at only one or a few of its conditions of use. Petitioners argue that, under TSCA, the Agency may only issue a “no unreasonable risk” determination for a chemical substance after it has considered the risks associated with *all* of that substance’s conditions of use.⁷

We hold that this challenge is not justiciable because Petitioners’ interpretation of what EPA intends to do and Petitioners’ resulting theory of injury are too speculative.

1.

“Article III of the Constitution empowers us to adjudicate only ‘live cases or controversies,’ not ‘to issue advisory opinions [or] to declare rights in hypothetical cases.’” *Clark v. City of Seattle*, 899 F.3d 802, 808 (9th Cir. 2018) (quoting *Thomas v. Anchorage Equal Rights Comm’n*, 220 F.3d 1134, 1138 (9th Cir. 2000) (en banc)). The requirement of Article III standing “aids the federal judiciary to avoid intruding impermissibly upon the powers vested in the executive and legislative branches, by preventing courts from issuing advisory opinions not founded upon the facts of a controversy between truly adverse parties.” *Scott v. Pasadena Unified Sch. Dist.*, 306 F.3d 646, 654 (9th Cir. 2002). For purposes of standing, a plaintiff must establish he or she has “(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and

⁷ No party discusses, so we do not reach, whether a broader evaluation of risks would be required to comply with 15 U.S.C. § 2605(a) at the regulation stage, if the predicate determination of unreasonable risk had been made based on fewer than all of a substance’s conditions of use.

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(3) that is likely to be redressed by a favorable judicial decision.” *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016).

An “injury in fact” is “an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992) (citations and quotation marks omitted). A “concrete” injury is one that “actually exist[s],” meaning that it is “real, and not abstract.” *Spokeo*, 136 S. Ct. at 1548 (quotation marks omitted). Both “[i]ntangible harms and a ‘risk of real harm’ can be sufficiently concrete” for these purposes. *Bassett v. ABM Parking Servs., Inc.*, 883 F.3d 776, 779 (9th Cir. 2018) (quoting *Spokeo*, 136 S. Ct. at 1549–50). A “particularized” injury is one that “affect[s] the plaintiff in a personal and individual way.” *Spokeo*, 136 S. Ct. at 1548 (quoting *Lujan*, 504 U.S. at 560 n.1).

“Ripeness is [another] . . . doctrine[] that we use to determine whether a case presents a live case or controversy” over which we have jurisdiction under Article III. *Clark*, 899 F.3d at 808. Ripeness doctrine

is designed “to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect . . . agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.”

Ohio Forestry Ass’n, Inc. v. Sierra Club, 523 U.S. 726, 732–33 (1998) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 148–49 (1967), *abrogated on other grounds by Califano v.*

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Sanders, 430 U.S. 99, 105 (1977)). Because ripeness doctrine derived “both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction,” *Clark*, 899 F.3d at 809 (quoting *Thomas*, 220 F.3d at 1138), the “ripeness inquiry” has often involved “both ‘a constitutional and a prudential component,’” *id.* (quoting *Bishop Paiute Tribe v. Inyo County*, 863 F.3d 1144, 1153 (9th Cir. 2017)).

To satisfy the constitutional ripeness requirement, a case “must present issues that are definite and concrete, not hypothetical or abstract.” *Id.* (quoting *Bishop Paiute Tribe*, 863 F.3d at 1153). “[S]orting out where standing ends and ripeness begins is not an easy task,” *id.* (quoting *Thomas*, 220 F.3d at 1138), so “[c]onstitutional ripeness is often treated under the rubric of standing because ripeness coincides squarely with standing’s injury in fact prong,” *id.* (alteration in original) (quoting *Bishop Paiute Tribe*, 863 F.3d at 1153).

Where (as here) there is a judicial review provision in a statute, any prudential ripeness considerations are satisfied for cases brought under that provision.⁸ See *Ohio Forestry Ass’n*, 523 U.S. at 737 (citing TSCA’s judicial review provision in 15 U.S.C. § 2618 as an example of a statute in which Congress provided for pre-enforcement review, and suggesting that such a provision renders a pre-enforcement challenge prudentially ripe); see also *Shalala v. Ill. Council*

⁸ We noted in *Clark* that “[t]he Supreme Court . . . cast doubt on the prudential component of ripeness in *Susan B. Anthony List v. Driehaus*, [573 U.S. 149 (2014)].” 899 F.3d at 809 n.4. In *Clark*, like the Court in *Susan B. Anthony List*, we did not need to “resolve the continuing vitality of the prudential ripeness doctrine.” *Id.* (quoting *Susan B. Anthony List*, 573 U.S. at 167). The same is true here because any potential prudential ripeness concerns are resolved by TSCA’s judicial review provision.

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on *Long Term Care, Inc.*, 529 U.S. 1, 12–13 (2000) (referring to statutorily authorized pre-enforcement review as an exception to ripeness and exhaustion requirements, and likewise citing § 2618 as an example).

Although a judicial review provision like that in 15 U.S.C. § 2618 avoids any *prudential* ripeness concerns about claims brought under that provision, such a provision does not make a claim *constitutionally* ripe. The Supreme Court emphasized in *Spokeo* that Congress cannot confer Article III jurisdiction when it is otherwise lacking. *See Spokeo*, 136 S. Ct. at 1547–48 (“Injury in fact is a constitutional requirement, and ‘[i]t is settled that Congress cannot erase Article III’s standing requirements by statutorily granting the right to sue to a plaintiff who would not otherwise have standing.’” (alteration in original) (quoting *Raines v. Byrd*, 521 U.S. 811, 820 n.3 (1997))). And while *Spokeo* itself addressed Article III standing, the same is necessarily true of Article III ripeness, which is also a constitutional requirement. *See Stolt-Nielsen S.A. v. AnimalFeeds Int’l Corp.*, 559 U.S. 662, 670 n.2 (2010) (“Ripeness reflects constitutional considerations that implicate ‘Article III limitations on judicial power.’” (quoting *Reno v. Catholic Soc. Servs., Inc.*, 509 U.S. 43, 57 n.18 (1993))); *cf. Barenblatt v. United States*, 360 U.S. 109, 112 (1959) (“Congress . . . must exercise its powers subject to the limitations placed by the Constitution on governmental action.”). Petitioners must therefore establish that their case is justiciable under the Article III doctrines of standing and ripeness, with respect to each of their claims.

2.

a.

Petitioners argue that they are injured by the use-by-use approach of the Risk Evaluation Rule in two ways. First, Petitioners contend, the use-by-use approach will lead EPA to underestimate risk where exposure results from multiple activities involving a chemical, which threatens their concrete interests in avoiding harmful exposures to chemicals. Second, they argue that the Rule will deprive them of information about chemical risks to which they are entitled under TSCA and that they need to reduce exposures to toxic chemicals.⁹ Petitioners maintain that these injuries are imminent, noting, for example, that their members are currently exposed to a chemical flame retardant that is already undergoing risk evaluation. They also argue that their claims are ripe, pointing to TSCA's judicial review provision and the harm they argue would be caused by

⁹ Petitioners further argue that their members are injured by EPA's failure to follow the correct procedures. But Petitioners have not shown that EPA has actually failed to follow any specific procedures—at most, Petitioners' claim is that EPA has indicated, in promulgating the Risk Evaluation Rule, that it intends to not follow correct procedures. Even if that is so, the Agency has not yet taken a specific action that could have violated a procedural or statutory right (*e.g.*, by completing a risk evaluation without following procedures required by TSCA), so this case differs from ones arising out of alleged procedural injuries. *See, e.g., Friends of Santa Clara River v. U.S. Army Corps of Eng'rs*, 887 F.3d 906, 910 (9th Cir. 2018) (challenge under National Environmental Policy Act ("NEPA"), Endangered Species Act, and Clean Water Act to an agency's process in issuing a permit authorizing discharge of materials into a river); *Citizens for Better Forestry v. U.S. Dep't of Agric.*, 341 F.3d 961, 970 (9th Cir. 2003) (holding that the plaintiffs "were deprived of the opportunity to comment on the [agency's NEPA documents] at all points in the rulemaking process," and that "[t]his deprivation violated their rights under the regulations implementing NEPA").

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delaying the performance of risk evaluations that comply with TSCA.

EPA argues that Petitioners' claim is nonjusticiable because it is based merely on a "hypothes[is] about how EPA may apply [the Rule] in the future," and therefore Petitioners have not alleged "a concrete or particularized injury." EPA maintains that if it ever *does* take final agency action that Petitioners believe fails to comply with TSCA's requirements, then Petitioners could challenge that action. Intervenor agree with EPA that this claim is not justiciable, because the existence of the Risk Evaluation Rule itself could not possibly cause Petitioners any injury.

b.

We conclude that Petitioners' challenge regarding use-by-use risk evaluations is not justiciable because it is not clear, due to the ambiguous text of the Risk Evaluation Rule, whether the Agency will actually conduct risk evaluations in the manner Petitioners fear.

Petitioners rely heavily on the Rule's reference to "whether [a] chemical substance presents an unreasonable risk of injury to health or the environment *under each condition of use[]* within the scope of the risk evaluation." 40 C.F.R. § 702.47 (emphasis added). One reading of this provision (and its use of the term "each") does suggest that EPA will evaluate risks associated with conditions of use individually. But it does not *necessarily* mean that EPA will (or even could) make determinations of "no unreasonable risk" based only on individual use-by-use evaluations, rather than on an evaluation that looks at "each" condition—as in "every one of the" conditions—of use together.

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The same is true of the statement in 40 C.F.R. § 702.41(a)(9) that Petitioners challenge, which provides that “EPA will complete the risk evaluation of the chemical substance addressing all of the conditions of use within the scope of the evaluation.” This could well mean EPA will do exactly what Petitioners argue it must: consider all conditions of use before completing a risk determination for a chemical. It also states that “EPA may complete its evaluation of the chemical substance under specific conditions of use or categories of conditions of use at any point following the issuance of the final scope document, and issue its determination as to whether the chemical substance under those conditions of use does or does not present an unreasonable risk.” 40 C.F.R. § 702.41(a)(9). But again, although this suggests that EPA plans to conduct some use-by-use risk determinations, it does not clearly mean that EPA will fail to do what Petitioners argue is required under TSCA.

The last provision that Petitioners challenge, 40 C.F.R. § 702.49(d), is no different. There, the Rule states merely that “[a] determination by EPA that the chemical substance, under one or more of the conditions of use within the scope of the risk evaluation, does not present an unreasonable risk . . . will be issued by order and considered to be a final Agency action.” 40 C.F.R. § 702.49(d). We simply do not know what this provision means either, or how the Agency will apply it in any particular case.

Other provisions in the Rule are similarly ambiguous. One states:

In general, EPA intends to determine whether a chemical substance does or does not present an unreasonable risk under all of the conditions of use within the scope of the risk

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evaluations, and intends to identify the individual conditions of use or categories of conditions of use that are responsible for such determinations.

40 C.F.R. § 702.41(a)(8). Again, this might well mean that EPA will evaluate whether a substance poses an unreasonable risk under each use individually, or it might mean that the Agency will consider conditions of use collectively, as Petitioners wish. And a provision entitled “Final determination of unreasonable risk,” which appears immediately before the challenged § 702.49(d), states that EPA will regulate a substance if it determines that “under one or more of the conditions of use within the scope of the risk evaluation [the substance] presents an unreasonable risk of injury to health or the environment.” 40 C.F.R. § 702.49(c). This might comport with Petitioners’ understanding of TSCA’s requirements: that the relevant question is whether a chemical substance poses an unreasonable risk under any one condition of use, *or* under any combination of uses.

And, in fact, the preamble to the Risk Evaluation Rule weighs against Petitioners’ understanding of EPA’s plans, as it supports the notion that EPA will evaluate risks collectively, just as Petitioners wish: “[T]he Agency is to exercise [its] discretion consistent with the objective of conducting a technically sound, manageable evaluation to determine whether a chemical substance—not just individual uses or activities—presents an unreasonable risk.” Procedures for Chemical Risk Evaluation Under the

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Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726, 33,729 (July 20, 2017).¹⁰

The lack of clarity in what the regulations promulgated by EPA mean creates a justiciability problem with Petitioners' claim. To the extent it is not clear how EPA will actually conduct risk evaluations under these rules, there is no concrete, imminent harm to Petitioners' interests that is caused by the challenged provisions. On this point we look to two analogous contexts: pre-enforcement challenges to rules that proscribe certain behavior, and challenges to rules that confer benefits on individuals.

In the context of pre-enforcement challenges to agency rules governing the behavior of regulated parties, we have recognized that “[n]either the ‘mere existence of a proscriptive statute’ nor a ‘generalized threat of prosecution’ satisfies the ‘case or controversy’ requirement.” *Wolfson v. Brammer*, 616 F.3d 1045, 1058 (9th Cir. 2010) (quoting *Thomas*, 220 F.3d at 1139). Rather, “for a claim to be ripe, the plaintiff must be subject to a genuine threat of imminent prosecution.” *Id.* (quotation marks and emphasis omitted). In evaluating the existence of any such genuine threat, we look at three criteria: “(1) whether the plaintiff has articulated a concrete plan to violate the law in question; (2) whether the prosecuting authorities have communicated a specific warning or threat to initiate proceedings; and (3) the history of past prosecution or enforcement under the

¹⁰ By contrast, EPA has asserted in its briefing to our court that it has flexibility, under the Risk Evaluation Rule, to conduct use-by-use “no unreasonable risk” determinations. Elsewhere in its briefs, however, EPA contends that “[u]nder the [Risk Evaluation Rule], EPA will, in fact, issue final risk evaluations for entire chemical substances.” These contradictory statements add to the ambiguity about how EPA plans to conduct risk evaluations.

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challenged statute.” *Id.*; see also *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014) (“[W]e have held that a plaintiff satisfies the injury-in-fact requirement where he alleges ‘an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder.’” (quoting *Babbitt v. United Farm Workers Nat’l Union*, 442 U.S. 289, 298 (1979))).

In the context of “benefit-conferring rule[s],” *Mont. Env’tl. Info. Ctr. v. Stone-Manning*, 766 F.3d 1184, 1190 (9th Cir. 2014) (quoting *Reno*, 509 U.S. at 69 (O’Connor, J., concurring in the judgment)), we have applied a “firm prediction rule” to determine constitutional ripeness, *id.* Under that rule, drawn from Justice O’Connor’s concurring opinion in *Reno v. Catholic Social Services, Inc.* and adopted by our court in *Freedom to Travel Campaign v. Newcomb*, 82 F.3d 1431 (9th Cir. 1996), we ask whether we “can make a firm prediction that the plaintiff will apply for the benefit [at issue], and that the agency will deny the application by virtue of the [challenged] rule.” *Id.* at 1436 (quoting *Reno*, 509 U.S. at 69 (O’Connor, J., concurring in the judgment)).

While neither of these lines of cases speaks directly to the issue that we now face, both clearly aim to deduce, in different contexts, the extent to which a claimed injury is actually and non-speculatively impending. Applying the principles underlying each of these tests, we conclude that Petitioners’ challenge regarding use-by-use determinations is not justiciable. Because of the ambiguity in the rules, we cannot predict whether Petitioners will be harmed in the way they claim, or whether the Agency will in fact apply these rules as Petitioners wish.

Clark v. City of Seattle is also instructive in this regard. In *Clark*, Seattle’s city council passed an ordinance

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establishing a multistep collective bargaining process applicable to ride-hailing services. A group of drivers sued, challenging the legality of the ordinance, and we held that the challenge was not ripe under Article III. 899 F.3d at 809 n.4. Among other things, we noted that injury to the drivers was not actual or imminent, because it would occur only if a contract or agreement was in fact reached—and no such contract or agreement was near. *Id.* at 810–11. The assertion of injury was therefore “wholly speculative.” *Id.* at 811. Petitioners’ theory of injury in this case is even more speculative. In *Clark*, it was clear what the procedures would be but unclear whether they would actually be invoked. Here, it is not even clear what EPA’s procedures will be, let alone whether EPA will employ them in a way that injures Petitioners.

Because Petitioners’ theory of injury is dependent upon harm caused by a failure to assess all conditions of use together, and because it is very uncertain whether EPA ever plans to do what Petitioners fear, Petitioners’ alleged injury is too speculative at this time to establish Article III jurisdiction. *See Clinton v. City of New York*, 524 U.S. 417, 432 (1998) (emphasizing that plaintiffs must establish a “sufficient likelihood of . . . injury to establish standing”). If EPA *does*, in the future, fail to consider all conditions of use together in completing a risk evaluation, and if Petitioners are harmed by that failure, then Petitioners may, under TSCA, seek review of EPA’s “no unreasonable risk” determination. *See* 15 U.S.C. §§ 2618(a)(1)(A), 2605(i)(1).¹¹ Petitioners would at that time have standing to

¹¹ Likewise, to the extent EPA decides it has discretion under the Prioritization and Risk Evaluation Rules to consider risk on a use-by-use basis, and not holistically, and to the extent that decision affects the Agency’s prioritization decisions, Petitioners may challenge EPA’s

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sue, and such a claim would be ripe for review. And EPA has insisted—both at oral argument and in its briefing here—that Petitioners would be able to challenge an allegedly improper risk determination. *See* 15 U.S.C. § 2618(a)(1)(A).

B.

Petitioners next argue that the Risk Evaluation Rule contravenes TSCA’s requirement that EPA consider *all* of a chemical’s conditions of use when conducting a risk evaluation—which Petitioners assert is required whether or not Petitioners are correct in their argument, discussed above, that the risk analysis should look at uses collectively. Petitioners’ challenge relating to the proper scope of a risk evaluation comes in two forms: a challenge to preambular language, and challenges to provisions of the Risk Evaluation Rule (which we will refer to as the “scope provisions”).

First, Petitioners identify language in the preamble to the Risk Evaluation Rule that they contend reflects EPA’s intent not to consider every condition of use. For example, Petitioners direct our attention to EPA’s suggestion that it may exclude circumstances in which a substance is unintentionally present as an impurity in a second chemical from the risk evaluation of the substance present as the impurity, and may instead evaluate the risks associated with the impurity in the context of the second chemical. *See* 82 Fed. Reg. at 33,730. Petitioners also point to EPA’s suggestion that it may disregard the existence of that

designation of a particular substance as low-priority. *See* 15 U.S.C. §§ 2618(a)(1)(C)(i), 2605(b)(1)(B)(ii).

impurity entirely if its associated risk would be *de minimis*.
Id.

Second, Petitioners challenge several provisions of the Risk Evaluation Rule itself, relying to some extent on the preamble to support these claims. Specifically, Petitioners challenge the Risk Evaluation Rule's statement that "[t]he scope of the risk evaluation will include . . . [t]he condition(s) of use, as determined by the Administrator, that the EPA plans to consider in the risk evaluation." See 40 C.F.R. § 702.41(c). Petitioners also point to EPA's references in the Risk Evaluation Rule to the conditions of use "within the scope of" the evaluation, see 40 C.F.R. §§ 702.41(a)(5), (a)(8), (a)(9), (c)(4)(i), (c)(4)(iii), (d)(2); 702.49(b)–(d), arguing that this wording further shows that EPA does not intend to consider all conditions of use. Petitioners express similar concern about the provision on manufacturer-requested risk evaluations:

EPA will assess whether the circumstances identified in the request constitute condition [sic] of use under [the Risk Evaluation Rule's definition section], and whether those conditions of use warrant inclusion within the scope of a risk evaluation for the chemical substance. EPA will also assess what, if any, additional conditions of use that [sic] warrant inclusion within the scope of a risk evaluation for the chemical substance.

40 C.F.R. § 702.37(e)(3). Petitioners argue that these provisions demonstrate that not all conditions of use will be in the scope of a risk evaluation, and that EPA is asserting discretion to exclude some conditions of use.

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With respect to the challenged preambular language, we hold that it is not final agency action, and thus is not reviewable under the Administrative Procedure Act. We are left, then, with Petitioners’ challenges to specific provisions of the Risk Evaluation Rule. Although we conclude that these challenges are justiciable, we hold that they fail on the merits because the provisions that Petitioners point to do not, as Petitioners contend, in fact assert discretion to exclude conditions of use from evaluation.

1.

The Administrative Procedure Act gives courts the authority to review final agency action. *See* 5 U.S.C. § 704; *see also Nat. Res. Def. Council v. EPA*, 643 F.3d 311, 319 (D.C. Cir. 2011) (referring to finality as a “jurisdictional issue[]”). A final agency action is one that “mark[s] the consummation of the agency’s decisionmaking process,” and one “by which rights or obligations have been determined, or from which legal consequences will flow.” *U.S. Army Corps of Eng’rs v. Hawkes Co.*, 136 S. Ct. 1807, 1813 (2016) (quoting *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997)). Formally promulgated rules are the bread and butter of final agency actions. *See Dole v. United Steelworkers of Am.*, 494 U.S. 26, 33 (1990) (“The promulgation of a disclosure rule is a final agency action.”); *Cal. Sea Urchin Comm’n v. Bean*, 828 F.3d 1046, 1049 (9th Cir. 2016) (“The 1987 Final Rule was clearly a final agency action.”). A regulation’s “preamble may under some circumstances be reviewable” as final agency action. *Kennecott Utah Copper Corp. v. U.S. Dep’t of Interior*, 88 F.3d 1191, 1222 (D.C. Cir. 1996); *see also Ctr. for Biological Diversity v. Nat’l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1181 n.1 (9th Cir. 2008) (“We do not address this issue since the parties agreed . . . that the preemption

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discussion in the preamble of the Final Rule is not final agency action and thus not currently reviewable.”). “The question of reviewability hinges upon whether the preamble has independent legal effect, which in turn is a function of the agency’s intention to bind either itself or regulated parties.” *Kennecott*, 88 F.3d at 1223. Even “[a]bsent an express statement [of intent], we may yet infer that the agency intended the preamble to be binding if what it requires is sufficiently clear.” *Id.*

In the preamble to the Risk Evaluation Rule, the Agency noted that based on its reading of TSCA, it “may, on a case-by-case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern.” 82 Fed. Reg. at 33,729. The Agency indicated that it may do so when a risk associated with a use would be *de minimis*, or when another regulatory agency has already assessed that use. *Id.*

In a section of the preamble entitled “Conditions of use that may be excluded from the [s]cope of the risk evaluation,” *id.* at 33,730, EPA “elaborate[d] further on this,” *id.* at 33,729. There, EPA explained that it “intends to exercise discretion in addressing circumstances where [a] chemical substance . . . is unintentionally present as an impurity in another chemical substance that is not the subject of the pertinent scoping.” *Id.* at 33,730. In some circumstances, EPA stated, “it may be most appropriate . . . to evaluate the potential risks arising from a chemical impurity within the scope of the risk evaluations for the impurity itself,” while in others it “may be more appropriate to evaluate such risks within the scope of the risk evaluation for the separate chemical substances that bear the impurity.” *Id.* The Agency further provided that it “may choose not to

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include [that] impurity within the [s]cope of any risk evaluation,” where “the risk from the presence of the impurity would be ‘*de minimis*’ or otherwise insignificant.” *Id.* EPA also listed several other uses that commenters had suggested should not be considered in risk evaluations, including: “[u]ses where other agencies hold jurisdiction, misuse, illegal use, speculative future conditions of use, [or] uses that are inconsistent with labeling requirements.” *Id.* EPA ultimately concluded, however, that “it would be premature to definitively exclude a priori specific conditions of use from risk evaluation.” *Id.*

This is not the sort of language that indicates an agency has intended to bind itself—in fact, it appears to be just the opposite. The preambular language concerning the scope of risk evaluations indicates only that EPA could “exercise discretion” about the context in which it could evaluate a substance that is present as an impurity, and “*may* choose not to” ever consider the impurity when its risk would be *de minimis*. *See id.* (emphasis added); *see also Nat. Res. Def. Council v. EPA*, 559 F.3d 561, 565 (D.C. Cir. 2009) (emphasizing, in the context of evaluating finality, a distinction between “may” and “will”). The Agency referenced other uses that *commenters* had suggested should be excluded from the scope of a risk evaluation, but explicitly decided *not* to definitively exclude any “specific conditions of use,” explaining that it would make “reasonable, technically sound scoping decisions” with respect to each individual substance evaluated. 82 Fed. Reg. at 33,730. The preamble language does not bind the agency to *ever* exclude any conditions of use from consideration. It therefore is not reviewable as final agency action under the Administrative Procedure Act.

2.

We turn next to Petitioners' challenge to the scope provisions. These provisions, as part of the Rule itself, clearly qualify as final agency action, *see Cal. Sea Urchin Comm'n*, 828 F.3d at 1049, and we conclude that Petitioners' challenge to them is justiciable. Nonetheless, Petitioners' challenge fails on the merits. Even assuming TSCA requires EPA to consider all conditions of use within the scope of a chemical substance's risk evaluation, the provisions of the Risk Evaluation Rule that Petitioners challenge do not evince any contrary intent on the part of EPA.

a.

Looking first at Petitioners' standing to challenge the scope provisions of the Risk Evaluation Rule, Petitioners argue that they will imminently be harmed by EPA's exclusion of some conditions of use from consideration, because EPA will systematically understate risks associated with chemicals that are evaluated. Petitioners also argue that because (on their reading) the Risk Evaluation Rule allows EPA to avoid evaluating some potential risks associated with chemical substances, the Rule excludes necessary information from EPA's publications.¹²

As an initial matter, the challenged language here is not ambiguous, so it is not speculative whether the Rule authorizes EPA to do what Petitioners claim. This

¹² Because this challenge is to part of the Rule itself, which, as we have explained, undoubtedly constitutes final agency action, we need not consider whether the challenged language expresses the Agency's intent to bind itself for purposes of deciding whether we may review it. Because that language is in the formally promulgated Rule, rather than a preamble discussion, it by definition binds the Agency.

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differentiates it from Petitioners' challenge to use-by-use determinations which, as we explained above, is too speculative to evaluate. Moreover, to the extent Petitioners are correct both that the Risk Evaluation Rule asserts the Agency's discretion to exclude conditions of use and that TSCA forecloses the Agency from asserting such discretion, their alleged injuries would be caused by the challenged provisions. *See Nat. Res. Def. Council v. EPA*, 643 F.3d 311, 319–23 (D.C. Cir. 2011). Although, as we explain, we do not agree with Petitioners that the Rule provisions *actually* have the effect that Petitioners claim, this distinction bears not on Petitioners' standing but on the merits of their claim. *See Kirola v. City and County of San Francisco*, 860 F.3d 1164, 1175 (9th Cir. 2017) (Where a district court held that a plaintiff lacked standing because she “had not been deprived of meaningful access to a challenged service, program, or activity,” which was required to establish the claim alleged, the district court had “improperly conflated [the plaintiff's] standing with whether she would prevail on the merits.” (quotation marks omitted)); *see also Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990) (“Our threshold inquiry into standing ‘in no way depends on the merits of the [petitioner's] contention that particular conduct is illegal.’” (alteration in original) (quoting *Warth v. Seldin*, 422 U.S. 490, 500 (1975))). Petitioners therefore have standing to challenge these provisions, and that challenge is ripe.

b.

Petitioners' challenge to the Rule's scope provisions, however, fails on the merits. The problem with Petitioners' theory is that the meaning they attribute to these provisions is inconsistent with the provisions themselves. The phrase “the conditions of use within the scope of” an evaluation simply refers to the conditions of use that are applicable to

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any particular substance—and that therefore are included in the scope of that substance’s evaluation—without excluding any conditions of use in forming that list. Likewise, the phrase that refers to the conditions of use “that the EPA plans to consider” simply refers to the Agency’s role in determining what the conditions of use are for a particular substance. Petitioners effectively acknowledge as much in arguing that the similar language of TSCA itself referring to the conditions of use that the Administrator “expects to consider” *does not* grant EPA discretion to exclude conditions of use. *See* 15 U.S.C. § 2605(b)(4)(D). We see no reason why “plans to consider” should be read differently than “expects to consider.”

The provision on manufacturer-requested risk evaluations may lend some support to Petitioners’ contrary reading—at least to the extent it suggests that the question whether a circumstance constitutes a condition of use is separable from the question whether that condition of use “warrant[s] inclusion within” a risk evaluation’s scope. *See* 40 C.F.R. § 702.37(e)(3). But a more natural reading is that this refers, again, simply to the Agency’s discretion (and expertise) in determining what constitutes a condition of use for a particular chemical substance. We therefore conclude that the challenged provisions unambiguously do not grant EPA the discretion Petitioners contend. *See Encino Motorcars, LLC v. Navarro*, 138 S. Ct. 1134, 1143 (2018) (resolving a question of statutory interpretation based on “the best reading of the statute”); *Nat’l Cable & Telecomms. Ass’n v. Gulf Power Co.*, 534 U.S. 327, 333 (2002) (“This is our own, best reading of the statute, which we find unambiguous.”).

We recognize that to the extent a rule is ambiguous, its preamble—even if not itself reviewable as final agency

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action—may help explain the promulgating agency’s intent. *See City of Las Vegas v. FAA*, 570 F.3d 1109, 1117 (9th Cir. 2009) (“When a regulation is ambiguous, we consult the preamble of the final rule as evidence of context or intent of the agency promulgating the regulations.”); *El Comité Para El Bienestar de Earlimart v. Warmerdam*, 539 F.3d 1062, 1070 (9th Cir. 2008) (“[T]he preamble language should not be considered unless the regulation itself is ambiguous.”). But because the scope provisions are not ambiguous on their face, reference to the preamble discussion would be improper.

Petitioners also point to the ongoing evaluation of the chemical substance 1,4-dioxane, which is a byproduct created in manufacturing processes and also appears as a contaminant in consumer products. Petitioners contend that EPA’s approach to that evaluation is evidence that the Risk Evaluation Rule has the effect they fear.¹³ As Petitioners

¹³ EPA made the scope document for 1,4 dioxane publicly available online. *1,4-Dioxane Scope Document and Supplemental Files*, EPA, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/14-dioxane-scope-document-and-supplemental-files> (last updated June 22, 2017). We take judicial notice of this document. *See* Fed. R. Evid. 201; *Lee v. City of Los Angeles*, 250 F.3d 668, 688–89 (9th Cir. 2001) (explaining that “a court may take judicial notice of matters of public record” under Rule 201 (quotation marks omitted)); *see also Sierra Club v. EPA*, 762 F.3d 971, 975 & n.1 (9th Cir. 2014) (taking judicial notice of EPA “public guidance” under Rule 201). We otherwise deny as moot Petitioners’ motion to complete the administrative record. *See TSG Inc. v. EPA*, 538 F.3d 264, 272 n.4 (3d Cir. 2008) (denying as moot a motion to expand the administrative record because the documents at issue did “not alter [the court’s] holding”); *Bd. of Regents of Univ. of Wash. v. EPA*, 86 F.3d 1214, 1222 (D.C. Cir. 1996) (dismissing as moot a “Motion to Enlarge the Administrative Record on Review” because it “could have no effect on the outcome” of the case).

emphasize, EPA issued a scope document for 1,4-dioxane indicating that the Agency intends to exclude the production of 1,4-dioxane in a byproduct form from the scope of the risk evaluation for 1,4-dioxane, and intends instead to consider those activities in the scope of risk evaluations for other chemicals. But Petitioners' challenge in this action is to the Rule itself—not to EPA's 1,4-dioxane evaluation—and we do not interpret the language in the Rule to say anything about exclusion of conditions of use.¹⁴ Thus, even assuming the 1,4-dioxane scope document has the flaws Petitioners claim, those flaws would not result from the provisions of the Rule Petitioners challenge here.

We therefore conclude that Petitioners' challenge relating to excluding conditions of use from the scope of risk evaluations fails.

C.

Finally, we turn to Petitioners' challenge to EPA's categorical exclusion of legacy activities from the definition of "conditions of use."

TSCA defines the term "conditions of use" to mean: "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). The definition in the Risk Evaluation Rule parrots the statute. *See* 40 C.F.R. § 702.33. In the preamble to the Risk Evaluation Rule, EPA elaborated on this

¹⁴ As EPA emphasizes, Petitioners could challenge the exclusion of certain forms or uses of 1,4-dioxane in the context of that chemical substance's final risk determination.

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definition, however, and stated that it does not consider what it now calls “legacy activities”—consisting of “legacy uses,” “associated disposals,” and “legacy disposals”—to be conditions of use. *See* 82 Fed. Reg. at 33,729–30.

EPA defines the term “legacy uses” in the preamble as “the circumstances associated with activities that do not reflect ongoing or prospective manufacturing, processing, or distribution.” *Id.* at 33,729. For example, although asbestos is now infrequently used in making new insulation, it remains in place in previously installed insulation. According to EPA’s interpretation, the use of asbestos in insulation is a “legacy use” of that chemical. “Associated disposal[s]” refers to future disposals from legacy uses, *id.*, such as the removal of asbestos-containing insulation to a landfill during a building’s renovation. Finally, “legacy disposal[s]” are defined as “disposals that have already occurred,” regardless of whether the substance disposed of is still manufactured for its pre-disposal use. *Id.* For example, this could refer to the previous placement of asbestos insulation into a landfill or the previous disposal of a chemical substance in a flame retardant that is still used for that purpose. Petitioners argue that EPA’s exclusion of these legacy activities from the definition of “conditions of use” contradicts TSCA’s clear statutory definition of the term.

Again addressing jurisdiction first, we agree with both Petitioners and EPA that this claim is justiciable. Proceeding to the merits, we hold that EPA’s exclusion of legacy uses and associated disposals contradicts TSCA’s plain language, but that EPA’s exclusion of legacy disposals does not.

1.

Petitioners argue that their challenge to EPA’s exclusion of each of the three types of legacy activities is justiciable.

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They contend that it is sufficiently clear that EPA has categorically excluded legacy activities from consideration as conditions of use, and that they will be harmed by these exclusions. As to this claim, EPA agrees with Petitioners that we have jurisdiction—conceding that Petitioners’ allegation that they will be harmed by risk determinations that do not include legacy activities “is a sufficient allegation for standing purposes,” and that the challenge is ripe because “EPA created a general presumption that it will not prioritize and evaluate existing chemicals under their legacy uses and disposals.” We agree.

Petitioners argue that their members are exposed to—and injured by—the use of chemical substances through legacy activities. For example, Petitioner United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union has members who, through their work, are exposed to the known carcinogen asbestos in the form of legacy uses when “equipment or structures are demolished, repaired[,] or refurbished.” Petitioners also argue that their members are at risk of exposure to asbestos through its associated disposal. Petitioners similarly claim that their members suffer harmful lead exposures resulting from the “legacy use” of lead paint and water pipes.

Petitioners have standing to challenge this exclusion, and their challenge is ripe. As Petitioners point out, EPA’s interpretation here is “definitional,” and generally “requir[es] EPA to ignore ongoing exposures from ‘legacy activities’ in *every* risk evaluation.” Petitioners claim that excluding these ongoing exposures from consideration will understate a chemical’s health risks, violating Petitioners’

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right to risk evaluations that comply with TSCA.¹⁵ They argue that this threatens their concrete interest in the health protections provided by TSCA. EPA's exclusion of legacy activities from the definition of "conditions of use" has the clear, immediate effect of excluding broad categories of activities from EPA's consideration in chemical risk evaluations, and Petitioners' alleged resulting injury is sufficiently clear and concretely tied to the challenged preamble to satisfy the requirements of both standing and ripeness.¹⁶

2.

In reviewing an agency's interpretation of a statute, we apply the standard articulated by the Supreme Court in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).¹⁷ See *Akhtar v. Burzynski*, 384 F.3d 1193, 1198 (9th Cir. 2004). Under *Chevron* step one, we ask "whether Congress has directly spoken to the precise question at issue." *Id.* At that point, "[i]f the intent of Congress is clear, that is the end of the matter; . . . [we]

¹⁵ Petitioners also argue that these exclusions will infect EPA's prioritization decisions.

¹⁶ Because this alleged injury alone is enough to support standing, we need not decide whether Petitioners could also assert an informational injury.

¹⁷ Because Congress delegated to EPA the authority to promulgate rules establishing a risk evaluation process, and because we conclude that the preamble language at issue here constitutes final agency action, it is evaluated under *Chevron* because "it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001).

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must give effect to the unambiguously expressed intent of Congress.” *Id.* (quoting *Chevron*, 467 U.S. at 842–43). But if “the statute is silent or ambiguous with respect to the specific issue, we must ask” at *Chevron* step two “whether the regulations promulgated by the agency are based on a permissible construction of the statute.” *Id.* If they are, we “must defer to the agency.” *Id.* We need not defer to agency regulations, however, “if they construe a statute in a way that is contrary to congressional intent or that frustrates congressional policy.” *Id.*

a.

As an initial matter, we note that although EPA’s exclusion of legacy activities appears in the preamble to the Risk Evaluation Rule rather than in the text of the rule itself, EPA concedes that its “preamble interpretation regarding legacy activities is reviewable because it is a binding statutory interpretation that EPA stated it intends to apply going forward.” We agree. EPA definitively “resolve[d] the [asserted] statutory ambiguity” in the definition of “conditions of use” when it announced in the preamble that it would exclude legacy activities. 82 Fed. Reg. at 33,730. EPA specifically stated that it “interpret[ed] [TSCA’s] mandates” to be inapplicable to legacy activities, and accordingly “interpret[ed] the definition” of “conditions of use.” *Id.* This interpretation was EPA’s final, unequivocal interpretation—there is every reason to believe that the Agency intended to bind itself, and what is required by this interpretation is, as EPA concedes, sufficiently clear to be

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reviewable.¹⁸ We therefore may evaluate the preamble's exclusion of legacy activities as final agency action.

b.

TSCA defines “conditions of use” as “the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” 15 U.S.C. § 2602(4). Interpreting this statutory text in the preamble to the Rule, EPA relied on what it understood to be TSCA’s “focus on uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (*i.e.*, is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal.” 82 Fed. Reg. at 33,730. As evidence, EPA pointed to the “to be” phrasing in TSCA’s definition of “conditions of use.” *Id.* EPA also noted that TSCA’s legislative history focuses on the regulation of chemicals “in commerce.” *Id.* Finally, the Agency stated that TSCA does not authorize it to regulate uses of chemicals except by regulating chemicals’ manufacture, processing, or distribution. For example, although EPA could regulate the production of a flame retardant for use in home furniture, the Agency contends in its briefing here that it could not prevent individuals who already own furniture treated with that flame retardant from

¹⁸ The preamble to the Prioritization Rule similarly stated, in definitive terms: “EPA has determined that certain activities generally should not be considered to be ‘conditions of use.’” Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33,753, 33,755 (July 20, 2017).

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continuing to use that furniture. Together, such considerations led EPA to give TSCA a “prospective interpretation” that excludes legacy activities. *Id.*¹⁹

In defending its interpretation here, EPA draws on these explanations given in the preamble. EPA further argues that the terms “intended” and “reasonably foreseen” as used in TSCA’s definition of “conditions of use” “are plainly forward looking”; that “known,” when combined with “to be,” is a “present tense verb”; and that “intended,” “known,” and “reasonably foreseen” are all “broad, general terms that plainly require EPA to exercise its judgment.” This language, EPA contends, demonstrates that Congress intended EPA to focus on activities for which the manufacturing, processing, or distribution in commerce of a chemical is intended, known, or reasonably foreseen. EPA also argues that it would make little sense to interpret conditions of use to include activities that EPA has little time to evaluate or ability to regulate, and that TSCA should be interpreted to allow the Agency to focus on quickly regulating the worst risks, which it contends do not arise from legacy activities.

Petitioners argue that EPA’s interpretation is contradicted by the plain text of TSCA’s statutory definition of “conditions of use,” and is not saved by any grant of unfettered discretion to the Agency. Petitioners argue that

¹⁹ In the preamble, EPA also concluded that its interpretation finds “support in the general presumption against construing a statute (or implementing regulation) to be retroactive or have retrospective effect.” 82 Fed. Reg. at 33,730. It noted that “[w]hile Congress can make a law retroactive, absent clear intent from Congress, courts will not hold a statute to be retroactive, or uphold an agency regulation that seeks to have such an effect.” *Id.* EPA does not rely on this argument in responding to this Petition for Review.

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EPA’s interpretation, which only includes the use and subsequent disposal of chemicals that *also* continue to be manufactured, processed, or distributed in commerce for that same use, fails to give independent meaning to “use” and “disposal” in the statutory definition’s disjunctive list (“manufactured, processed, distributed in commerce, used, *or* disposed of”). For instance, Petitioners note, “lead pipes are ‘known to be used’ in water distribution systems,” and “[t]his is true regardless of whether lead pipes continue to be manufactured or distributed.” Petitioners also argue that an interpretation that “would result in inconsistent treatment of identical activities based solely on whether manufacture or distribution is ongoing,” as EPA’s would, does not square with TSCA itself.²⁰ Petitioners dispute EPA’s claim that, when a substance is no longer manufactured or distributed for a particular use, it is unable to evaluate or regulate that use and associated disposal, and argue that even if EPA’s assertions to that effect were correct, that would not necessitate a finding that EPA could therefore exclude consideration of such use and disposal from risk evaluations. They further argue that because previously disposed substances continue to be present at disposal sites, their disposal is ongoing, and captured by TSCA’s definition. Finally, Petitioners generally contend that EPA’s exclusion of legacy activities “undermine[s] TSCA’s core aim to prevent unreasonable risks to health and the environment from toxic chemicals.”

²⁰ Petitioners point out that EPA has previously promulgated regulations under TSCA to protect against exposure to legacy uses of asbestos. *See* 40 C.F.R. § 763.120–.123.

c.

EPA’s contention that TSCA can reasonably be read to refer to the future use of a product, and disposals associated with such use, *only* when the product will also be manufactured in the future for that use—and not when the product is no longer manufactured for the relevant use—is without merit. TSCA’s “conditions of use” definition plainly addresses conditions of use of chemical substances that will be used or disposed of in the future, regardless of whether the substances are still manufactured for the particular use.

Although we agree with EPA that the phrase “to be” in the statutory definition denotes the present or future tense, when “to be” is combined with “used” and “disposed of,” two plain meanings result: future uses, and future disposals. And these are precisely the things that EPA has purported to exclude by defining conditions of use to exclude legacy uses and associated disposals: activities (*i.e.*, uses), “that do not reflect ongoing or prospective manufacturing, processing, or distribution,”²¹ and “disposals from such uses,” such as “the future disposal of insulation that contains a chemical substance that is no longer manufactured, processed, or distributed for use in insulation.” *See* 82 Fed. Reg. at 33,729.

²¹ Petitioners argue that EPA’s own prior definitions of “use” in the context of chemical substances support this understanding, and argue that EPA’s exclusion of “legacy use” from conditions of use represents an unexplained departure from these prior interpretations. We need not decide whether EPA’s prior definitions of “use” in its regulations are in any way binding on the Agency here, because “use” has a plain meaning within TSCA that, as we explain, clearly encompasses the sorts of things that EPA categorizes as “legacy uses.”

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The example used by EPA in the Risk Evaluation Rule’s preamble—the disposal of insulation previously installed in a building—in fact serves as a useful example for why the Agency’s interpretation cannot be upheld: The *future* disposal of asbestos insulation is clearly an example of a chemical substance being “disposed of.” To the extent it is “intended” that such a substance be disposed of, or “known” that it will be, or if such disposal is “reasonably foreseen,” that circumstance unambiguously falls within TSCA’s definition of “conditions of use.” Similarly, as Petitioners point out, if lead pipes exist in water distribution systems, they are “known to be used” in those systems. This is so without any regard to whether these substances are *also* intended, known, or reasonably foreseen to be prospectively manufactured (or processed, or distributed in commerce) for those uses. *See* 15 U.S.C. § 2602(4) (referring to substances that will be “manufactured, processed, distributed in commerce, used, *or* disposed of” (emphasis added)); *see also* *Loughrin v. United States*, 573 U.S. 351, 357 (2014) (noting that the use of the term “or” “is almost always disjunctive, that is, the words it connects are to be given separate meanings” (quoting *United States v. Woods*, 571 U.S. 31, 45 (2013))).

EPA resists this conclusion, arguing that the Agency has broad discretion, granted to it by TSCA, to determine what constitutes a condition of use.²² We agree that the statute

²² EPA adds that although it has determined it is not *required* to consider legacy activities in evaluating chemical substances, it *may* do so where appropriate. As Petitioners point out, however, this does not save the legacy exclusion if legacy activities are conditions of use that EPA is required—rather than just permitted—to consider in risk evaluations. Regardless, a plaintiff’s challenge to an agency’s unambiguous assertion, in the context of a final agency action, of discretion to choose between two alternatives, when one is clearly

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grants EPA discretion to determine the conditions of use for each chemical substance, but that discretion may only be exercised within the bounds of the statutory definition itself. *See Massachusetts v. EPA*, 549 U.S. 497, 533 (2007) (explaining that a statute directing an agency to use its “judgment” did not grant the agency “a roving license to ignore the statutory text,” but rather directed the agency to “exercise discretion within defined statutory limits”). Where Congress has explicitly provided a definition for a term, and that definition is clear, an agency must follow it. And here, as we have explained, TSCA’s definition of “conditions of use” clearly includes uses and future disposals of chemicals even if those chemicals were only historically manufactured for those uses.²³ EPA’s exclusion of legacy uses and associated disposals from the definition of “conditions of use” is therefore unlawful.²⁴

disallowed by statute and, if chosen, would injure the plaintiff, is justiciable. *See Nat. Res. Def. Council v. EPA*, 643 F.3d 311, 319–22 (D.C. Cir. 2011). The agency’s assertion of discretion would, under those circumstances, be impermissible. *Id.* at 322.

²³ This conclusion is bolstered by the fact that TSCA elsewhere distinguishes between “active” substances—meaning those that have been manufactured or processed since 2006—and “inactive” substances—those that have not. TSCA did not, in calling for chemical risk evaluations, similarly distinguish between active and inactive chemical substances. *Compare* 15 U.S.C. § 2607(b)(4)(A)(ii)–(iii), *with* 15 U.S.C. § 2605. This suggests that Congress intended to make even inactive substances subject to prioritization and risk evaluation.

²⁴ To the extent the exclusion is incorporated into EPA’s Prioritization Rule, it is also unlawful.

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d.

We draw a distinction, however, between “legacy uses” and “associated disposals,” on the one hand, and “legacy disposals,” on the other. EPA uses the term “legacy disposals” to refer to “disposals that have already occurred (*e.g.*, a chemical substance currently in a landfill or in groundwater).” 82 Fed. Reg. at 33,729. As to this issue, EPA’s present tense argument has more force, and we hold that its interpretation is permissible under TSCA.

In our view, TSCA unambiguously does not require past disposals to be considered conditions of use. The statutory definition, once again, covers the circumstances “under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” 15 U.S.C. § 2602(4). A substance that has already been disposed of will not ordinarily be intended, known, or reasonably foreseen to be prospectively manufactured, processed, distributed in commerce, used, or (again) disposed of. Of course, there may be some substances that already have been disposed of yet are *also* “known . . . to be . . . distributed in commerce” or used. 15 U.S.C. § 2602(4). And TSCA’s definition does, as discussed above, clearly cover those substances and those prospective uses. But TSCA does not address a substance that has already been disposed of and remains so.

Petitioners argue that “disposal” in this context “is not a one-time occurrence when the substance . . . is buried or placed in a landfill or other waste facility,” but rather that disposal “remains ongoing after the initial act of discard.” By way of example, Petitioners note that although TSCA itself does not define the term “disposal,” EPA has previously defined the term in the context of regulating

chemicals known as PCBs, under the pre-2016 TSCA. In that context, EPA defines “disposal” to mean “intentionally or accidentally to discard, throw away, or otherwise complete or terminate the useful life of PCBs and PCB Items,” and specifically notes that “[d]isposal includes spills, leaks, and other uncontrolled discharges of PCBs as well as actions related to containing, transporting, destroying, degrading, decontaminating, or confining PCBs and PCB Items.” 40 C.F.R. § 761.3. EPA takes issue with Petitioners’ reliance on this definition, but acknowledges in its briefing here that the term “disposed of” could refer to “the act of putting something in a landfill or other resting place, or it could conceivably refer to the movement of chemicals by natural forces after the initial act of disposal.”

We need not wade into any debate over the precise meaning of “disposal.” Even accepting Petitioners’ asserted definition, we see no reason why “spills, leaks, and other uncontrolled discharges”—or even “actions related to containing . . . or confining” substances as also referenced in 40 C.F.R. § 761.3—would not be considered *independent* disposals. They would thus qualify as “disposals” (and therefore conditions of use) for substances that are currently manufactured for their pre-disposal use, or “associated disposals” for substances that are no longer manufactured for their pre-disposal use. If, under the applicable definition of “disposal,” something is in fact *again* disposed of—even if it was disposed of previously—or when a disposal is *in fact ongoing*, we see no reason why that use is not captured as a prospective disposal. But that does not mean that legacy disposals—as used to refer simply to “disposals that have already occurred”—should fall under the statutory definition of “conditions of use.”

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Because TSCA’s statutory definition of “conditions of use” unambiguously does not reach legacy disposals, we hold that the Agency did not err in excluding such disposals from consideration as “conditions of use.” *See Chevron*, 467 U.S. at 842–43 (“If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.”).

III.

For the reasons discussed, the Petition for Review is **DISMISSED** in part, **GRANTED** in part, and **DENIED** in part.²⁵ The Petition is dismissed with respect to Petitioners’ challenge regarding use-by-use determinations. The Petition is granted with respect to Petitioners’ challenge to EPA’s exclusion of “legacy uses” and “associated disposals” from the definition of “conditions of use,” and those portions of the Risk Evaluation Rule’s preamble are vacated. The Petition is denied with respect to the alleged exclusion of conditions of use from the scope of risk evaluation and with respect to EPA’s exclusion of “legacy disposals” from “conditions of use.” The parties shall bear their own costs on appeal.

²⁵ In the concurrently filed memorandum disposition addressing Petitioners’ challenge to information-gathering provisions of the Prioritization and Risk Evaluation Rules, we further deny the Petition in part and remand in part.